

REMARKS/ARGUMENTS

Reconsideration of this application is respectfully requested.

I. Status of the Application

Claims 204 - 206, 208 - 212, 214 - 241, and 243 - 247 are pending, with claims 1 - 203, 207, 213, 242 and 248 - 253 having been previously canceled. Applicant cancels claims 215 - 238 without prejudice or disclaimer, and amends claims 204 - 206, 209, 210, 214, 239, 241, 244 and 245. No new matter is introduced.

II. Examiner Interview

Applicant thanks Examiner Morgan for holding an in-person interview with Applicant and Applicant's representative on April 30, 2008. During this interview, Applicant described the reduction to practice of his invention as provided to the general public via the web site thebody.com, and provided additional explanation and context for Declarations previously prepared and submitted with Responses of August 19, 2004 and October 31, 2007 that detail and provide evidence of the time of reduction to practice. The scope of independent claims 204, 210, 239 was also discussed. Applicant thanks Examiner for his suggestions regarding further amendments to the claims to more clearly convey the scope of Applicant's invention, which are reflected in the amendments made to the claims herein. Applicant also thanks Examiner Morgan for considering and confirming that the Declarations of August 19, 2004 and October 31, 2007 provide adequate evidence as to the time or reduction to practice of Applicant's invention as embodied in thebody.com.

Timeline of the Reduction to Practice

No later than May 24, 1999

Applicant makes at least the following pages accessible to members of the public as a mechanism for volunteering to be considered as participants in clinical trials, headlined as follows, and begins collecting registrations:¹

http://www.thebody.com/surveys/health_survey.html "Volunteer for Research!"²

http://www.thebody.com/surveys/health_survey1.html "Volunteer for Research!/Participation Agreement"³

http://www.thebody.com/surveys/health_survey2a.ihtml "Health Survey"⁴

http://www.thebody.com/surveys/health_remove.ihtml "Removing Your Name from *The Body's* List of Volunteers for Research"⁵

June 28, 1999

Dr.Koop.com and Quintiles transmit a press release via Newswire ("Newswire).

On or about September 1,1999

Applicant begins collecting registrations of physicians interested in serving as clinical researchers of investigative drugs, at the following page.

¹ Exhibit C, 1st Goldman Declaration

² Exhibits G, I, Andrews Declaration (*two separate backups of this file, dated 5/24/99*); Exhibit Q, 2nd Goldman Declaration (*capture with graphics by archive.org dated 10/2/99*).

³ Exhibits H, J, Andrews Declaration (*two separate backups of this file, dated 5/24/99, with headline "Volunteer for Research! Participation Agreement"*); Exhibit R, 2nd Goldman Declaration (*capture with graphics by archive.org dated 7/12/2000, with revised headline "Applying for Clinical Studies and Research/Participation Agreement"*).

⁴ Exhibit L, 2nd Marks Declaration, beginning at page 8.

⁵ Exhibit P, 2nd Goldman Declaration (*capture with graphics by archive.org dated 9/12/99*); Exhibits C-F, Andrews Declaration (*source code from two separate backups of each of two files all dated 5/24/99, showing links from two web site pages to http://www.thebody.com/surveys/health_remove.ihtml*).

Summary of Evidence in Support of the Timeline

As shown by the above timeline, no later than **May 24, 1999**, Applicant made accessible to members of the public the pages with the headlines “Volunteer for Research!,” “Volunteer for Research!/Participation Agreement,” “Health Survey,” and “Removing Your Name from *The Body’s* List of Volunteers for Research,” as mechanisms enabling members of the public to self-enroll be considered as participants in clinical trials and to withdraw from participation if so desired. The pages were in all in good working order and resulted in collection of personally identifying information and medical data from actual volunteers as early as **May 24, 1999**, well in advance of the publication of Newswire on **June 28, 1999** and the earliest U.S. patent application filing by Michelson (the ‘634 Application) on **January 28, 2000**. Applicant made accessible to physicians the page “Research Opportunities for Physicians” as a mechanism for enrolling clinical researchers on or about September 1, 1999, and received at least one physician enrollment by **September 2, 1999**, well in advance of the filing of Michelson’s ‘634 Application on **January 28, 2000**.

On August 19, 2004, Applicants mailed a Response to Non-Final Office Action which disqualified the Newswire reference by demonstrating by Declarations of the inventor and others familiar with the invention that the date of invention preceded the publication date of the Newswire reference (June 28, 1999). Copies of the Response of August 19, 2004, together with copies of the Declarations of James D. Marks (Exhibit 1), Bonnie Goldman (Exhibit 2), Dahlia Elsayed (Exhibit 3), and Jason K. Dewey (Exhibit 4), which were enclosed with the Response of August 19, 2004, were most recently enclosed with a Preliminary Amendment of October 31, 2007. Associated Exhibits A - D, which provide copies of certain documents described in Exhibits 1 - 4, were most recently enclosed with the Response of August 19, 2004. A second Declaration of James D. Marks (Exhibit 5), a second Declaration of Bonnie Goldman (Exhibit 6) and a Declaration of Christopher Andrews (Exhibit 7) were enclosed with the Preliminary Amendment of October 31, 2007, together with copies of associated Exhibits A - J and L - R.

Applicant encloses Appendix I with the present Response , which provides a summary evidence presented in the Declarations demonstrating that the web pages described above as being

of the elements of pending claims 204 - 206, 208 - 212, 214, 239 - 241, and 243 - 247 finds support in the Applicant's Declarations. Attachment III clearly demonstrates that the invention as claimed was reduced to practice prior to Michelson's effective date of **January 28, 2000**. In addition, Applicant demonstrates that the invention as claimed in claims 245 - 247 was reduced to practice prior to Newswire's effective date of **June 28, 1999**.

Accordingly, Applicant respectfully submits that because Michelson (and, for claims 245 - 247, Newswire) have an effective date that falls after Applicant's reduction to practice of the claimed invention, these references fail to qualify as prior references with regard to each of pending claims 204 - 206, 208 - 212, 214, 239 - 241, and 243 - 247, and must therefore be removed. Applicant submits that pending claims 204 - 206, 208 - 212, 214, 239 - 241, and 243 - 247 therefore are allowable for at least this reason, and respectfully requests that the rejections of pending claims 204 - 206, 208 - 212, 214, 239 - 241, and 243 - 247 under 35 U.S.C. §§ 102, 103 be withdrawn.

**ATTACHMENT I:
WEBPAGES OPERABLE AT THEBODY.COM
AS OF MAY 29, 1999**

1. “Volunteer for Research” Page

Title: “Volunteer for Research”

Location: http://www.thebody.com/surveys/health_survey.html

Illustrations: Andrews Declaration, Exhibit G; 2nd Goldman Declaration, Exhibit Q

Evidence of reduction to practice as of May 24, 1999:

“I found [the file] labeled as follows on [website backup tapes] A01 [and] ... on A02: http://www.thebody.com/surveys/health_survey.html[.] ... I confirmed that the file system metadata states the date on which the [file was] created and, assuming the system clock was accurate on the machine that copied the original data to the tapes, confirmed that [the file was] created on May 24, 1999.

Andrews Declaration, paragraphs 9, 10 and 11.

“As of May 24, 1999 at the latest, the Health Survey Questionnaire accessible to members of the public included at least the following web site [page] posted at www.thebody.com: The page headlined, “Volunteer for Research” at http://www.thebody.com/surveys/health_survey.html (substantially in the form attached as Exhibit G of the Declaration of Christopher Andrews)....”
2nd Goldman Declaration, paragraph 6.

“The [page] posted at TheBody.com headlined, “Volunteer for Research” ... in addition to being substantially in the form of [Exhibit] G ... in the Declaration of Christopher Andrews, [was] moreover as of May 24, 1999 substantially in the form later captured at archive.org (showing .jpg graphics) on October 2, 1999 ... at the following [URL]: http://web.archive.org/web/19991002035408/http://www.thebody.com/surveys/health_survey.html.... and [is] attached ... in current hardcopy form as [Exhibit] Q.”
2nd Goldman Declaration, paragraph 8.

2. “Volunteer for Research!/Participation Agreement” Page

Title: “Volunteer for Research!/Participation Agreement”

Location: http://www.thebody.com/surveys/health_survey1.html

Illustrations: Andrews Declaration, Exhibit H; 2nd Goldman Declaration, Exhibit R

Evidence of reduction to practice as of May 24, 1999:

“I found [the file] labeled as follows on [website backup tapes] A01 [and] ... on A02: http://www.thebody.com/surveys/health_survey1.html[.] ... I confirmed that the file system metadata states the date on which the [file was] created and, assuming the system clock was accurate on the machine that copied the original data to the tapes, confirmed that [the file was] created on May 24, 1999.

Andrews Declaration, paragraphs 9, 10 and 11.

“As of May 24, 1999 at the latest, the Health Survey Questionnaire accessible to members of the public included at least the following web site [page] posted at www.thebody.com: The page headlined, “Volunteer for Research!/Participation Agreement” at http://www.thebody.com/surveys/health_survey1.html (substantially in the form attached as Exhibit H of the Declaration of Christopher Andrews)....”

2nd Goldman Declaration, paragraph 6.

“The [page] posted at TheBody.com headlined, “Volunteer for Research!/Participation Agreement” ... in addition to being substantially in the form of [Exhibit] H ... in the Declaration of Christopher Andrews, [was] moreover as of May 24, 1999 substantially in the form later captured at archive.org (showing .jpg graphics) on October 2, 1999 ... at the following [URL]:

http://web.archive.org/web/20000712022808/http://www.thebody.com/surveys/health_survey1.html.... and [is] attached ... in current hardcopy form as [Exhibit] R.”

2nd Goldman Declaration, paragraph 8.

**ATTACHMENT II:
WEBPAGES OPERABLE AT THEBODY.COM
AS OF SEPTEMBER 1, 1999**

5. Physician Registration Page

Title: "Research Opportunities for Physicians"

Location: <http://www.thebody.com/surveys/physicians.html>

Illustrations: 2nd Marks Declaration, Exhibits M - O

Evidence of reduction to practice as of September 1, 1999:

I further conceived of, supervised and controlled the design and implementation of a web site page on www.thebody.com headlined, "Research Opportunities for Physicians," (the Physician Registration Page) at which BHRC invited registration of physicians interested in serving as clinical researchers of investigative drugs. The page was substantially in the form captured on January 18, 2000 at archive.org (an entity independent of BHRC), ...and which may be viewed currently at

<http://web.archive.org/web/20000118011618/http://thebody.com/surveys/physicians.html>
2nd Marks Declaration, paragraph 10, 11.

[A] form letter and enclosures used in a September 1, 1999 mailing from BHRC [] invited physician registration. The form letter encloses a copy of the upper portion of the Physician Registration Page as an illustration, and a response post card which was provided as an alternative to registering online. [Post] cards sent in the promotional mailing, filled out and returned by physicians, [show] U.S.P.S. cancellation stamps of September 2 and September 3, 1999. Upon information and belief, the Physician Registration Page was available to the public at <http://www.thebody.com/surveys/physicians.html> on or about September 1, 1999.
2nd Marks Declaration, paragraph 10.

**ATTACHMENT III
 SUPPORT FOR CLAIMS PROVIDED BY DECLARATIONS
 INDEPENDENT CLAIMS**

Claim Elements	Declaration Support
<p>204. A method of acquiring information from individuals who want to volunteer for ongoing consideration as potential candidates for participating as research subjects in any of a plurality of clinical trials, by means of a server operated by a recruitment service provider, the server being configured to communicate with a plurality of end-user computer terminals via a network, the method comprising the steps of:</p>	<ul style="list-style-type: none"> • An announcement provided in a web page entitled "Volunteer for Research," was created and archived no later than May 24, 1999 (Declaration of Christopher Andrews, page 3). In an announcement made on May 26, 1999, thebody.com announced that it will act as a recruitment service provider by compiling a database including information about volunteers volunteering for possible participation in medical trials (Declaration of James D. Marks, pgs. 4, 5). • the body.com operated on leased server space hosted by Interport Communications Corp. (Declaration of Bonnie Goldman, pg. 3) • Multiple responses to a Health Survey Questionnaire for recruitment posted by the body.com, most likely received at and transmitted by a plurality of end-user terminals, were received at thebody.com as of May 25, 1999 (Declaration of Jason K. Dewey, pg. 2). The Health Survey Questionnaire was made accessible via the "Volunteer for Research" web page, each of which was available no later than May 24, 1999 (Declaration of Christopher Andrews, page 3 and Exhibit I, Second Declaration of Bonnie Goldman, page 2).

Claim Elements	Declaration Support
wherein registration of the individual precedes registration of one or more of the plurality of clinical trials.	<ul style="list-style-type: none"><li data-bbox="786 373 1401 520">• Health Survey Questionnaire responses were stored beginning no later than May 24, 1999 (Declaration of Bonnie Goldman, pg. 4)<li data-bbox="786 533 1401 861">• A solicitation of physician investigators conducting clinical trials began no later than September 1, 1999 (Second Declaration of James D. Marks, pg 4). This solicitation was facilitated by a web page entitled "Research Opportunities for Physicians," accessible to the general public via thebody.com (Second Declaration of James D. Marks, pg 3).

Claim Elements	Declaration Support
<p>239. A method of on-line recruitment of individuals who want to volunteer with a recruitment service provider for ongoing consideration as potential candidates for participating as research subjects in any of a plurality of clinical trials, by means of a server operated by the recruitment service provider, the server being configured to communicate with a plurality of end-user computer terminals via a network, the method comprising the steps of:</p>	<ul style="list-style-type: none"> • An announcement provided in a web page entitled "Volunteer for Research," was created and archived no later than May 24, 1999 (Declaration of Christopher Andrews, page 3). In an announcement made on May 26, 1999, thebody.com announced that it will act as a recruitment service provider by compiling a database including information about volunteers volunteering for possible participation in medical trials (Declaration of James D. Marks, pgs. 4, 5). • the body.com operated on leased server space hosted by Interport Communications Corp. (Declaration of Bonnie Goldman, pg. 3) • Multiple responses to a Health Survey Questionnaire for recruitment posted by the body.com, most likely received at and transmitted by a plurality of end-user terminals, were received at thebody.com as of May 25, 1999 (Declaration of Jason K. Dewey, pg. 2). The Health Survey Questionnaire was made accessible via the "Volunteer for Research" web page, each of which was available no later than May 24, 1999 (Declaration of Christopher Andrews, page 3 and Exhibit I, Second Declaration of Bonnie Goldman, page 2).

Claim Elements	Declaration Support
wherein registration of the individual precedes registration of one or more of the plurality of clinical trials.	<ul style="list-style-type: none"><li data-bbox="781 373 1404 520">• Health Survey Questionnaire responses were stored beginning no later than May 24, 1999 (Declaration of Bonnie Goldman, pg. 4)<li data-bbox="781 537 1404 867">• A solicitation of physician investigators conducting clinical trials began no later than September 1, 1999 (Second Declaration of James D. Marks, pg 4). This solicitation was facilitated by a web page entitled "Research Opportunities for Physicians," accessible to the general public via thebody.com (Second Declaration of James D. Marks, pg 3).

Claim Elements	Declaration Support
<p>245.: A method by which an individual may register as a volunteer to be considered on an ongoing basis for selection as a potential candidate for participating as a research subject in any of a plurality of clinical trials, and by which the individual may subsequently opt out of the registration, by means of a server operated by a recruitment service provider, the server being configured to communicate with a plurality of end-user computer terminals via a network, the method comprising the steps of:</p>	<ul style="list-style-type: none"> • An announcement provided in a web page entitled "Volunteer for Research," was created and archived no later than May 24, 1999 (Declaration of Christopher Andrews, page 3). In an announcement made on May 26, 1999, thebody.com announced that it will act as a recruitment service provider by compiling a database including information about volunteers volunteering for possible participation in medical trials (Declaration of James D. Marks, pgs. 4, 5). • thebody.com operated on leased server space hosted by Interport Communications Corp. (Declaration of Bonnie Goldman, pg. 3). • Thebody.com included a web page entitled "Removing Your Name from <i>The Body's</i> List of Volunteers for Research" (the Removal page), which was accessible from the web page entitled "Volunteer for Research," and available no later than May 24, 1999 (Second Declaration of Bonnie Goldman, pgs. 3, 4, Declaration of Christopher Andrews, pgs. 3, 4). • Multiple responses to a Health Survey Questionnaire for recruitment posted by the body.com, most likely received at and transmitted by a plurality of end-user terminals, were received at thebody.com as of May 25, 1999 (Declaration of Jason K. Dewey, pg. 2). The Health Survey Questionnaire was made accessible via the "Volunteer for Research" web page, each of which was available no later than May 24, 1999 (Declaration of Christopher Andrews, page 3 and Exhibit I, Second Declaration of Bonnie Goldman, page 2).

Claim Elements	Declaration Support
<p>providing a participation agreement for display on one of the plurality of end-user computer terminals accessible to the individual, the participation agreement soliciting consent from the individual to be considered on an ongoing basis for selection as a potential candidate for participating as a research subject in any of the plurality of clinical trials ;</p>	<ul style="list-style-type: none"> • A web page entitled “Volunteer for Research/Participation Agreement” providing access to a Participation Agreement for display on an end-user terminal was available at thebody.com and archived as early as May 24, 1999 (Second Declaration of Bonnie Goldman, pgs. 3, 4, Declaration of Christopher Andrews, page 3). • The Participation Agreement indicates that an individual participant is consenting to allow the recruitment service provider to provide information from the Health Survey Questionnaire to clinical researchers for the purpose of being matched with clinical studies and considered as a participant for an appropriate clinical trial (Exhibit J, pgs. 1 - 3, 5)
<p>receiving a signal from the one end-user computer terminal indicating the individual’s consent to the participation agreement;</p>	<ul style="list-style-type: none"> • The Participation Agreement included an “I accept” button which was selectable by clicking on the button at the user terminal to provide electronic consent (Exhibit J, pg. 5) • Non-receipt of the electronic consent at the server precluded acceptance of a Health Survey Questionnaire response by the recruitment service provider (Second Declaration of James D. Marks, pg. 4)

Claim Elements	Declaration Support
the server storing the personally-identifying information of the individual and information indicating the individual's request to withdraw the registration in the database.	<ul style="list-style-type: none"><li data-bbox="781 373 1393 661">• Prior to May 24, 1999, staff of thebody.com were instructed to periodically download and store withdrawal requests, and to delete stored Health Survey Questionnaire for registered individuals associated with the withdrawal requests (Second Declaration of Bonnie Goldman, pg 4).

**ATTACHMENT III
 SUPPORT FOR CLAIMS PROVIDED BY DECLARATIONS
 DEPENDENT CLAIMS**

Claim Elements	Declaration Support
<p>Claim 205. The method of claim 204, wherein the individual's agreement signifies an agreement by the individual to release the contact information to a representative of any one or more of the plurality of clinical trials.</p>	<ul style="list-style-type: none"> • A web page entitled "Volunteer for Research/Participation Agreement" providing access to a Participation Agreement for display on an end-user terminal was available at thebody.com and archived as early as May 24, 1999 (Second Declaration of Bonnie Goldman, pgs. 3, 4, Declaration of Christopher Andrews, page 3). • The Participation Agreement indicates that an individual participant is consenting to allow the recruitment service provider to provide information from the Health Survey Questionnaire to clinical researchers for the purpose of being matched with clinical studies and considered as a participant for an appropriate clinical trial (Exhibit J, pgs. 1 - 3, 5). • The Health Survey Questionnaire solicited contact information, other personal information and medical information (Second Declaration of James D. Marks, pg. 2 and Exhibit L, pgs. 1 - 6).
<p>Claim 206. The method of claim 204, wherein the health survey form solicits identification of one or more medical conditions of the individual relevant to one or more of the plurality of clinical trials.</p>	<ul style="list-style-type: none"> • The Health Survey Questionnaire solicited contact information, other personal information and medical information (Second Declaration of James D. Marks, pg. 2 and Exhibit L, pgs. 1 - 6).
<p>Claim 208. The method of claim 204, wherein the network comprises one or more of the Internet, the World Wide Web, an intranet, a local area network, a wide area network and a wireless communications network:</p>	<ul style="list-style-type: none"> • No later than May 24, 1999, thebody.com server posted the Health Survey Questionnaire for access via the Internet (Declaration of Bonnie Goldman, pg. 2).

Claim Elements	Declaration Support
<p>Claim 214. The method of claim 210, wherein the first information transmitted by the individual signifies an agreement by the individual to release the contact information to a representative of any one or more of the plurality of clinical trials.</p>	<ul style="list-style-type: none"> • A web page entitled “Volunteer for Research/Participation Agreement” providing access to a Participation Agreement for display on an end-user terminal was available at thebody.com and archived as early as May 24, 1999 (Second Declaration of Bonnie Goldman, pgs. 3, 4, Declaration of Christopher Andrews, page 3). • The Participation Agreement indicates that an individual participant is consenting to allow the recruitment service provider to provide information from the Health Survey Questionnaire to clinical researchers for the purpose of being matched with clinical studies and considered as a participant for an appropriate clinical trial (Exhibit J, pgs. 1 - 3, 5). • The Health Survey Questionnaire solicited contact information, other personal information and medical information (Second Declaration of James D. Marks, pg. 2 and Exhibit L, pgs. 1 - 6).
<p>Claim 240. The method of claim 239, wherein the participation agreement is a click-wrap agreement.</p>	<ul style="list-style-type: none"> • A web page providing access to a Participation Agreement for display on an end-user terminal was available at thebody.com as early as May 24, 1999 (Second Declaration of Bonnie Goldman, pgs. 3, 4) • The Participation Agreement provides a click-wrap “I accept” button signifying consent to the agreement (Exhibit J, pg. 5).
<p>Claim 241. The method of claim 239, wherein the health survey form solicits the identification of one or more medical conditions of the individual relevant to one or more of the plurality of clinical trials</p>	<ul style="list-style-type: none"> • The Health Survey Questionnaire solicited contact information, other personal information and medical information (Second Declaration of James D. Marks, pg. 2 and Exhibit L, pgs. 1 - 6).

Claim Elements	Declaration Support
<p>Claim 243. The method of claim 239, wherein the network comprises one or more of the Internet, the World Wide Web, an intranet, a local area network, a wide area network and a wireless communications network.</p>	<ul style="list-style-type: none"> No later than May 24, 1999, thebody.com server posted the Health Survey Questionnaire for access via the Internet (Declaration of Bonnie Goldman, pg. 2).
<p>Claim 244. The method of claim 239, further comprising the step of: providing registration information for display on a second end-user computer terminal, said registration information soliciting information for registering a clinical researcher to participate in one or more of the plurality of clinical trials.</p>	<ul style="list-style-type: none"> A solicitation of physician investigators conducting clinical trials began no later than September 1, 1999 (Second Declaration of James D. Marks, pg 4). This solicitation was facilitated by a web page entitled "Research Opportunities for Physicians," accessible to the general public via thebody.com (Second Declaration of James D. Marks, pg 3).
<p>Claim 246. The method of claim 245, wherein the personally-identifying information includes a name of the individual in combination with a second personal identifier of the individual.</p>	<ul style="list-style-type: none"> The Removal page was operable to receive the name of a registered individual, and to transmit this information operation of a "submit" button on the Removal Page (Second Declaration of Bonnie Goldman, pg 3).
<p>Claim 247. The method of claim 246, wherein the second personal identifier is a date of birth of the individual.</p>	<ul style="list-style-type: none"> The Removal page was operable to receive identifying information (a "birthdate") of a registered individual, and to transmit this information operation of a "submit" button on the Removal Page (Second Declaration of Bonnie Goldman, pg 3).